

Pharmanex, Inc. 625 Cochran Street Simi Valley, California 93065-1939 805.582.9300 Fax 805.582.9301

Margh 23, 1998 98 MAR 31 P3:08

## BY FEDERAL EXPRESS

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration 200 C. St. S.W. Washington, DC 20204 3/23/98)

RE: Notification for Certain Types of Statements on Dietary Supplements.

Dear Sir or Madam:

As required by Section 403 (r)(6)(c) of the Food, Drug and Cosmetic Act, Pharmanex Inc., 625 Cochran Street, Simi Valley, California 93065-1939, intends to market a dietary supplement product with the following labeling statements of nutritional support:

Product identified as **St. John's wort**, containing standardized extract of St. John's wort, with the following labeling statements:

- 1. Promotes healthy emotional balance.
- 2. Helps stabilize mood.
- 3. Promotes positive outlook.
- 4. St. John's wort extract has been clinically tested to help people maintain a healthy emotional balance and a positive outlook.
- 5. Pharmanex St. John's wort helps stabilize mood by modulating the brain's neurotransmitters (including dopamine and serotonin).
- 6. By promoting a healthy emotional balance, this formula may help you cope more effectively with the constant demands and stresses of modern life.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,

Sr. V.P. Research & Development

LET 1428 57887